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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,667	02/08/2002	Kathy K. Wang	OSTEONICS 3.0-380	4016
530 7590 12/06/2007 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER SHAFFER, RICHARD R	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 12/06/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/071,667

Applicant(s)

WANG ET AL.

Examiner

Richard R. Shaffer

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 9-13, 15-18, 79, 82-87, 89-93, 95-98 and 101-103 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 9-13, 15-18, 79, 82-87, 89-93, 95-98 and 101-103 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: NPL Document (Queheillalt et al).

DETAILED ACTION

In view of the Appeal Brief filed on September 14th, 2007, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:



EDUARDO J. ROBERT
SUPERVISORY PATENT EXAMINER

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 89 and 90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 89 recites the limitation "claim 88" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 88 has been cancelled.

Claim 90 is rejected for being dependent upon an indefinite base claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 11-13, 15-18, 79, 98, 101 and 102 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaplan (US Patent 5,282,861).

Kaplan discloses a porous biocompatible thick or thin (**Column 2, Lines 13-14**) metal (niobium or tantalum, **Column 3, Lines 24-25**) foam network comprising: an open cell structure (as seen in **Figure 1** and stated in **Column 6, Lines 30-35**) with a pore size of at least 150 microns for tissue in-growth and of almost any porosity (**Column 6, Line 33**). The cell openings can be controlled by the amount of metal deposited on the carbon foam forming a continuous web. The device is intended for use in orthopedic applications (**See Column 1, Line 7 through Column 3, Line 65**) and be locked about a core of solid tantalum or niobium (**Column 9, Lines 55-60**).

Applicant has repeatedly attempted to define over the prior art by recitation of the process (e.g. using particles of varying size, metal starting webs, and claiming a sintering process). Evidence in the form of an affidavit must be submitted to attempt to

overcome the reference which appears to disclose the claimed invention made by a different process.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 9, 10, 82-87, 89-93, 95-97 and 103 are rejected under 35 U.S.C.

103(a) as being unpatentable over Kaplan in view of Queheillalt et al (2001).

Kaplan discloses all of the claimed limitations except for the metal webs being thicker on a side thereof facing towards the tissue contacting surface, the metal webs walls having "openings," and the thickness of the scaffold about the core being 0.5mm to 5mm.

In regard to the wall openings (Page 8, Applicant's response filed on September 14th, 2007 describes that openings are only not present due to uniform coating in CVD versus line-of-sight) and thicker coating on one side versus the opposite, this is due to the process of a line-of-sight deposition from physical vapor deposition methodologies including applicant's disclosed low temperature arc vapor deposition (LTAVD).

Queheillalt et al teach (**Pages 1028 and 1029**) various methods of manufacturing closed and open cell metal foams such as melt gas injection, gas releasing particle decomposition, chemical vapor deposition, and physical vapor deposition (metal spray deposition, thermal evaporation, reactive sputtering and arc-vapor deposition). Various

benefits and disadvantages are taught relative to CVD and PVD methods. CVD allows for non-line of sight deposition, low initial cost of equipment, but difficult to implement in an environmentally satisfactory manner due to the least expensive (but still expensive) precursors being toxic and decomposing at low temperatures. PVD has a higher cost for initial equipment (due to high vacuum), line-of-sight deposition (thus thicker coating on the side directed towards the vapor spray), creates foams with multilayered or functionally graded metal ligaments and cheaper ongoing production (relative to CVD).

One having ordinary skill in the art at the time of invention would have recognized the art equivalents to both PVD and CVD for forming metal foam cell networks and select between them based upon initial cost, ongoing cost, environmental impact, ease of implementation, uniform or non-uniform coating and rate of deposition. One having ordinary skill in the art at the time of invention would have found it obvious to select PVD (such as arc vapor deposition) for creating the implant of Kaplan in order to avoid negative environmental impact, easier implementation, cheaper ongoing production cost and ability to create multilayered/functionally graded metal ligaments while accepting the reduced deposition rate, increased initial cost of equipment and line-of-sight deposition. By selecting arc vapor deposition, the device would inherently result in one side having a thicker coating than the opposite side, with the thicker side inherently capable of being placed facing towards the tissue. Also, due to the opposite side not being struck by particles for bonding, openings would be present (inherently) due to the use of a line-of-sight deposition.

In regard to the thickness of the scaffold about the core being 0.5mm to 5mm. Queheillalt et al teach that open celled foams do result in cell sizes ranging from 100 microns (0.1mm) to 5mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the claimed range for the porous layer about a solid core, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

Applicant's arguments filed September 14th, 2007 have been fully considered but they are not persuasive.

Applicant continues to assert that the method applicant utilizes creates a structure different than that of Kaplan (sintering versus CVD). It has and continues to be the examiner's position that the resultant claimed invention is anticipated by the implant of Kaplan which is made by a different method, yet yields the claimed invention's structure which is what is required to anticipate the claimed invention. Applicant must submit test data in the form of an affidavit to demonstrate otherwise because currently all applicant is making is unfounded assertions which are not persuasive.

Further, applicant erroneously states that Kaplan only discloses "thin films." While the coatings are applied in thin amounts, nothing is preventing one to continue forming a thick wall by allowing a longer time to pass in the coating process. **Column 2, Lines 13-14** support this due to the explicit statement of thin or thick coatings.

Applicant also argues that Kaplan does not have hollow metal web walls. Clearly, since carbon is not a metal, and metal is coating a carbon core, then the metal "webs" are hollow with a carbon core placed in the hollow portion:

In regard to applicant's arguments of coatings thicker on one side versus the opposite as well as openings in the web walls, the points are moot in view of the new grounds of rejection of Kaplan in view of Queheillalt et al teaching the equivalence of PVD to CVD which would result in the structure claimed due to a line-of-sight deposition. Applicant's assertion in the arguments on Page 8 stating that Kaplan teaches away from applicant's process, it is noted that PVD is not sintering nor plasma-spraying and therefore not addressed as a method undesirable besides a line-of-sight deposition causing non-uniform (more on one side versus another) coating. However, due to the numerous considerations one must make in deciding between the two methods, as long as such does not destroy the primary reference, there are many reasons why one having ordinary skill in the art would sacrifice uniform coating for the cheaper and easier to implement process of PVD.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

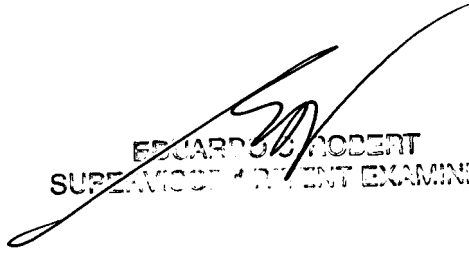
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Richard Shaffer
December 1st, 2007



EDUARDO ROBERT
SUPERVISOR PATENT EXAMINER